

**REMARKS**

**Examiner interview summary**

A telephonic Examiner interview with Attorney of record was conducted on February 12, 2005. In response to a restriction, a provisional election was made without traverse to prosecute the invention of Group 1, Claims 1-13 and 19-34 and cancel with claims of group II, Claims 14-18. This response serves to affirm this election. The applicant reserves the right to prosecute the cancelled claims or similar claims in the future.

**Rejection Under 35 USC 112**

Claims 1 and 19 have been rejected under 35 USC 112 as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Without acquiescing to the arguments raised by the Examiner (and, in order to further the business interests of the Applicant) the Applicant has amended the pending independent claims.

**Rejection Under 35 USC 103(a)**

Claims 1-13 and 19-34 have been rejected under 35 USC 103 as being unpatentable over U.S. Patent No. 6,329,564 B1 to Lebner in view of U.S. Patent No. 5,979,450 to Baker, et al. (since Claims 2-13 and 20-34 are dependent upon independent Claims 1 and 19, respectively, this response will address the rejection as it pertains to Claims 1 and 19). More specifically, the Patent Office states:

Regarding Claims 1, 9, 19 and 27 each of Lebner's anchoring members (5 and 25) have adhesive for sticking to the skin [column 5, lines 45-54, Fig 3] and connecting members (15 and 35) extending therefrom. "Protective film" is attached to adhesive backed surface of the each anchoring member [column 6, lines 13-15]. Lebner does not disclose a semi rigid tab as set forth in Claims 1 and 19.

However, Baker discloses a very similar polymer wound dressing with adhesive for application to skin adjacent an incision. Baker teaches a "relatively stiff" handle (22) protruding from the edge of "flexible" film (16). The flexible film/"liner" (16) covers the adhesive (14). Baker explains that in this art often when applying a polymer wound dressing "drape", because of the flimsy nature of the materials

used often the polymer becomes wrinkled during the application process and such a shoddy application "may not prevent bacteria on the skin from getting into the wound". He teaches having a handle – both on the "drape" and on the release liner (16) in order to allow quick, easy, and wrinkle-free application of an adhesive backed wound covering. Therefore, it would have been obvious to one having ordinary skill in the art to modify Lebner's wound closure device to have handles – both on the drape part and on the release liner part- in order to allow one surgeon to rapidly and cleanly apply the wound closure device, as taught by Baker.

A cursory review of the claimed invention and the cited prior art may suggest that an obviousness rejection of the type advanced has merit. However, a more detailed analysis reveals that not only is Applicant's invention not taught or suggested by the cited prior art but, in fact, the cited prior art teaches away from Applicant's disclosed invention. Applicant's Claims 1 and 19 have been amended to highlight this teaching away by the cited prior art. More specifically, paragraph 29 of the application as filed states that:

With respect to the flip tab two-stage release liner system, it is important that when the semi-rigid tab is flipped-back on to the portion of the release liner to which it is not attached by adhesive, that the portion of the release liner to which the tab is not attached remains fully adhered to the anchoring member.

Claims 1 and 19 have been amended to recite this feature. Operationally, this limitation describes the establishment of a reinforced "application control edge" on each of the adhesive backed anchoring members which is parallel to the wound edge. The application control edge is established by flipping back the semi-rigid tab (i.e., the first stage of the two stage release liner system). This application control edge enables a user to bend, for example, the first adhesive-backed anchoring member into a U-shape such that only a central portion of the first wound edge of the first anchoring member makes initial contact with the skin. The remaining portion of the first wound edge is then adhered in a very controlled manner by relaxing the U-shaped bend. Achieving the U-shape requires the additional reinforcement provided by the semi-rigid tab as all other parts are soft & flexible.

Baker teaches away from this establishment of an application control edge in numerous statements in the cited patent. First, contrary to the statement of the Patent Office, the Baker patent describes a device which is applied by two individuals cooperating simultaneously. One individual is controlling the film handle (18) and the second individual is controlling the liner

handle (22) (see column 16, lines 53-57). Thus, in the Baker invention, an individual physically controls the leading edge of the film by holding a handle attached to the leading edge of the film. In the present invention, on the other hand, the leading edge of the film (the wound edge of an adhesive-backed anchoring member) is controlled at a distance, by a single user, by virtue of the fact that the semi-rigid tab attached to the release liner, when flipped back onto the portion of the release liner to which it is not attached by adhesive, that the portion of the release liner to which the tab is not attached remains fully adhered to the anchoring member. Figure 1B of the Baker patent clearly demonstrates that the important limitation introduced into Applicant's Claims 1 and 19 is not met.

The proposed combination of Lebner and Baker teaches away from Applicant's invention in other important aspects as well. For example column 8 lines 45-66 make clear that it is not essential to the Baker invention that the liner handle (18) be stiff. Lines 57-58, for example, make clear that the liner handle (18) may be made of the same material as the liner (16). Such a material selection would be inconsistent with Applicant's invention and, therefore, represents a teaching away.

Rejection Under 35 USC 103(a)

Claims 2, 4, 20 and 22 have been rejected under 35 USC 103(a) as being unpatentable over U.S. Patent No. 6,329,564 B1 to Lebner in view of U.S. Patent No. 5,979,450 to Baker et al. Claims 2 and 4 are dependent on Claim 1 and Claims 20 and 22 are dependent on Claim 19. It is respectfully submitted that, from the standpoint of a rejection under 35 USC 103, Applicant's arguments as set forth above in connection with Claims 1-13 and 19-32 apply with equal force to the rejection of Claims 2, 4, 20 and 22. However, Applicant concedes that clarity relating to the pulling element limitation of Claims 2, 4, 20 and 22 could be enhanced by amendment and Applicant is prepared to make such amendments if a rejection is made under 35 USC 112.

Rejection Under 35 USC 103(a)

Claims 8 and 26 have been rejected under 35 USC 103(a) as being unpatentable over U.S. Patent No. 6,329,564 B1 to Lebner in view of U.S. Patent No. 5,979,450 to Baker et al. Claim 8 is dependent on Claim 1 and Claim 26 is dependent on Claim 19. It is respectfully

submitted that, from the standpoint of a rejection under 35 USC 103, Applicant's arguments as set forth above in connection with Claims 1-13 and 19-32 apply with equal force to the rejection of Claims 8 and 26.

Rejection Under 35 USC 103(a)

Claims 3, 5-7, 10-12, 21, 23-25, 28-30 and 32 have been rejected under 35 USC 103(a) as being unpatentable over U.S. Patent No. 6,329,564 B1 to Lebner in view of U.S. Patent No. 5,979,450 to Baker et al. Claims 3, 5-7, 10-12 are dependent on Claim 1 and Claims 21, 23-25, 28-30 and 32 are dependent on Claim 19. It is respectfully submitted that, from the standpoint of a rejection under 35 USC 103, Applicant's arguments as set forth above in connection with Claims 1-13 and 19-32 apply with equal force to the rejection of Claims 3, 5-7, 10-12, 21, 23-25, 28-30 and 32.

Rejection Under 35 USC 103(a)

Claims 13 and 31 have been rejected under 35 USC 103(a) as being unpatentable over U.S. Patent No. 6,329,564 B1 to Lebner in view of U.S. Patent No. 5,979,450 to Baker et al. Claims 13 is dependent on Claim 1 and Claims 31 is dependent on Claim 19. It is respectfully submitted that, from the standpoint of a rejection under 35 USC 103, Applicant's arguments as set forth above in connection with Claims 1-13 and 19-32 apply with equal force to the rejection of Claims 13 and 31.

Summary

In light of the above amendment, consideration of the subject patent application is respectfully requested. Any deficiency or overpayment should be charged or credited to Deposit Account No. 500282.

Respectfully submitted,



Kevin M. Farrell  
Attorney for Applicants  
Registration No. 35,505  
(603) 433-6300

Portsmouth, NH

Date: 8/22/05

P0069726.DOC